CHAPTER 5

QUALITY ASSURANCE

The quality assurance (QA) program at the West Valley Demonstration Project (WVDP) provides for and documents consistency, precision, and accuracy in collecting and analyzing environmental samples and in interpreting and reporting environmental monitoring data.

Organizational Responsibilities

West Valley Nuclear Services Company (WVNS) is contractually obligated to implement a nuclear quality assurance program at the WVDP. Managers of programs, projects, and tasks are responsible for determining and documenting the applicability of quality assurance requirements to their activities and for implementing those requirements. For example, Environmental Laboratory management and staff are directly responsible for carrying out sampling and analytical activities in a manner consistent with good quality assurance practices and for following approved procedures.

Program Design

The quality assurance rule 10 CFR Part 830.120, Quality Assurance (U.S. Department of Energy [DOE] 1998), and DOE Order 414.1, Quality Assurance (U.S. Department of Energy 1998) provide the quality assurance program policies and requirements applicable to activities at the WVDP. The integrated quality assurance program applicable to environmental monitoring at the WVDP also incorporates requirements from Quality Assurance Program Requirements for Nuclear Facilities (American Society of Mechanical Engineers [ASME NQA-1] 1989) and Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (American National Standards Institute and American Society for Quality Control [ANSI/ASQC E4-1994] 1994).

The quality assurance program focuses upon assigning responsibilities and upon thorough planning, specification, control, and documentation of all aspects of an activity in order to ensure the quality of both radiological and nonradiological monitoring data. The quality assurance program includes requirements in the following areas:

• *Responsibility*. Responsibilities involved in overseeing, managing, and conducting an activity must be clearly defined. Personnel who verify that the activity has been completed correctly must be independent of those who performed it.

• *Planning*. An activity must be planned beforehand and the plan followed. All activities must be documented. Similarly, purchases of any equipment or items must be planned, specified precisely, and verified for correctness upon receipt.

• *Control of design, procedures, items, and documents.* Any activity, equipment, or construction must be clearly described or defined and tested, and changes in the design must be tested and documented. Procedures must clearly state how activities will be conducted. Only approved procedures may be used. Equipment or particular items affecting the quality of environmental data must be identified, inspected, calibrated, and tested before use. Calibration status must be clearly indicated. Items that do not conform to requirements must be identified and separated from other items and the nonconformity documented.

• *Documentation.* Records of all activities must be kept in order to verify what was done and by whom. Records must be clearly traceable to an item or activity.

• *Corrective action.* If a problem should arise the cause of the problem must be identified, a corrective action planned, responsibility assigned, and the problem remedied.

• *Audits.* Scheduled audits and assessments must be conducted to verify compliance with all aspects of the quality assurance program and determine its effectiveness.

Subcontractor laboratories providing analytical services for the environmental monitoring program are contractually required to maintain a quality assurance program consistent with WVDP requirements.

Procedures

Those activities that affect the quality of environmental monitoring data are conducted according to approved procedures that clearly describe how the activity should be performed and what precautions are to be taken in connection with the activity. Any person performing an activity that could affect the quality of environmental monitoring data is trained in that procedure and must demonstrate proficiency. New procedures are developed each time an activity is added to the monitoring program. Procedures are reviewed periodically and updated when necessary. Documents are controlled so that only current procedures are used.

Quality Control in the Field

Quality control (QC), an integral component of environmental monitoring quality assurance, is a way of verifying that samples are being collected and analyzed according to established quality assurance procedures. Quality control ensures that sample collection and analysis are consistent and repeatable and is a means of tracking down possible sources of error. For example, at the WVDP sample locations are clearly marked in the field to ensure that future samples are collected in the same locations; collection equipment in place in the field is routinely inspected, calibrated, and maintained; and automated sampling stations are kept locked to prevent tampering and to ensure sample integrity.

Samples are collected into certified pre-cleaned containers of an appropriate material and capacity and are labeled immediately with the pertinent information. Date, time, person doing the collecting, and special field sampling conditions are recorded and kept as part of the record for that sample.

Chain-of-custody protocols are followed to ensure that samples are controlled and tracked for traceability. If necessary, samples are preserved as soon as possible after collection.

In order to assess quality problems that might be introduced by the sampling process, duplicate field samples, field blank samples, and trip blank samples are collected. Background samples are collected for baseline environmental information.

Field Duplicates. Field duplicates are samples collected simultaneously for the same analyte at one location, after which they are treated as separate samples. If the sampling matrix is homogenous, field duplicates provide a means of assessing the precision of collection methods. Field duplicates are collected at a minimum rate of one per twenty analyses.

Field Blanks. A field blank is a sample of laboratory-distilled water that is put into a sample container at a field collection site and is processed from that point as a routine sample. Field blanks are used to detect contamination introduced by the sampling procedure. They are processed at a minimum rate of one per twenty analyses.

If the same collection equipment is used for more than one site, a special form of field blank known as an equipment blank may be collected by pouring laboratory-distilled water through cleaned collecting equipment and into a sample container. Equipment blanks are collected to detect any cross-contamination that may be passed from one sampling location to another by the equipment. Many wells and surface water collection stations have dedicated collecting equipment that remains at that location; equipment blanks are not necessary at these locations.

Trip Blanks. Trip blanks are prepared by pouring laboratory-distilled water into sample bottles in the laboratory. The bottles are then placed into sample coolers where they remain throughout the sampling event. Trip blanks are collected in order to detect any volatile organic contamination that may be introduced from handling during collection, storage, or shipping. Trip blanks are taken only when volatile organic samples are being collected.

Environmental Background Samples. To monitor each pathway for possible radiological contamination, samples of air, water, vegetation, meat, and milk are taken from locations remote from the site for comparison with samples from near-site locations. Samples that are clearly outside site influence show ambient radiological concentrations and serve as backgrounds or "controls," another form of field quality control sample. Background samples provide baseline information to compare with information from near-site or on-site samples so that any possible influence from the site can be determined.

Quality Control in the Laboratory

More than 11,000 samples were handled as part of site monitoring in 1998. Samples for routine radiological analysis were analyzed on-site, with the rest being sent to subcontract laboratories. Off-site laboratories must maintain a level of quality control as specified in contracts with WVNS. Subcontract laboratories are required to participate in all applicable crosscheck programs and to maintain all relevant certifications.

In order to monitor the accuracy and precision of data, laboratory quality control practices specific to each analytical method are clearly described in approved references or procedures. Examples of laboratory quality control activities at the WVDP include proper training of analysts, maintaining and calibrating measuring equipment and instrumentation, and processing samples in accordance with specific methods as a means of monitoring laboratory performance.

Analytical instruments and counting systems are calibrated at specified frequencies and logs of instrument calibration and maintenance are kept. Calibration methods for each instrument are specified in procedures or in manufacturers' directions. Standards traceable to the National Institute of Standards and Technology (NIST) are used to calibrate counting and test instrumentation.

Laboratory quality control samples consist of three general types: standards (including spikes), used to assess accuracy; blanks, to assess the possibility of contamination; and duplicates, to assess precision.

Standards. Laboratory standards are materials containing known concentrations of an analyte of interest such as a pH buffer or a plutonium-239 counting standard. Standards used at the WVDP for environmental monitoring activities are either NIST-traceable or reference materials from other nationally recognized sources. At a minimum, one reference standard is analyzed for every twenty sample analyses. The results of the analyses are plotted on control charts, which specify acceptable limits. If the results lie within these limits, then analysis of actual environmental samples may proceed and the results are deemed usable.

Spikes. Another form of standard analysis is a laboratory spike. In a laboratory spike, a known amount of analyte is added to a sample or blank before the sample is analyzed. The percent recovery of the analyte indicates how much of the analyte of interest is being detected in the analysis of actual samples; hence, a spike also is an assessment of the accuracy of the method. Spike recoveries are recorded on control charts with documented acceptance limits.

Blanks. Laboratory blanks are prepared from a matrix similar to that of the sample but known to contain none of the analyte of interest. For instance, distilled water, taken through the same preparatory procedure as a sample, may serve as a laboratory blank for both radiological and chemical analyses of water samples. A positive result for an analyte in a blank indicates that something is wrong with the analysis and that corrective action should be taken. In general, one laboratory blank is processed daily or with each batch of samples for a given analyte.

A special form of laboratory blank for radiological samples is an instrument background count, which is a count taken of a planchet or vial containing no sample. The count serves three purposes: to determine if contamination is present in the counting instrument; to determine if the instrument is responding in an acceptable manner; and to determine the background correction that should be applied when calculating radiological activity in certain samples.

Environmental samples containing little or no radioactivity must be measured with very sensitive instruments. For example, gross alpha and gross beta measurements must be made with a low-background proportional counter. An instrument background count is taken before each day's counting or with each batch of twenty samples. Background counts are recorded on control charts with defined acceptance limits. An unacceptable count requires corrective action before analyses can proceed.

Duplicates. Duplicates are analyzed to assess precision in the analytical process. Laboratory duplicates are created by splitting existing samples before analysis; each split is treated as a separate sample. If the analytical process is in control, results for each split should be within documented acceptance criteria.

Crosschecks. WVNS participates in formal radiological crosscheck programs conducted by the U.S. Department of Energy (DOE) and the U.S.Environmental Protection Agency (EPA). The DOE requires all organizations performing effluent or environmental monitoring to participate in the semiannual Environmental Measurements Laboratory (EML) Quality Assessment Program (QAP), which is designed to test the quality of environmental measurements being reported to the DOE by its contractors. WVNS also participates in crosscheck programs from the EPA's National Exposure Research Laboratory, Environmental Sciences Division (NERL-ESD).

An informal crosscheck, which compared results from WVDP environmental thermoluminescent dosimeters (TLDs) to results from NRC TLDs placed in the same locations, was discontinued in 1998. Another informal crosscheck program uses results from samples of air filters, water, milk, fish, vegetation, and sediments that have been split or separately collected and sent to NYSDOH for independent measurement. (Co-located samples are listed in Appendix B of this report.) Results from NYSDOH are compared with WVDP results as an independent verification of environmental monitoring program data.

Crosscheck samples for radiological analyses are analyzed by both the Environmental Laboratory on-site and by the subcontract laboratory. Results from radiological crosschecks are summarized in Appendix J, Tables J-1 through J-3 (pp.J-3 through J-8). A total of 162 radiological crosscheck analyses were performed by or for the WVDP and reported in 1998. One hundred fifty-five results (95.7%) were within control limits. Forty-one of the results were produced by the on-site Environmental Laboratory; 97.6% were within control limits.

Results of nonradiological EPA crosschecks are summarized in Appendix J, Table J-4 (p.J-9). Twenty-one parameters were analyzed by Ecology and Environment, Inc. and two by WVDP. Of the twenty-three results, seventeen (73.9%) were within control limits. Out-of-control results were followed up through formal corrective action processes.

By contract with WVNS, subcontract laboratories are required to perform satisfactorily on crosschecks, defined as 80% of results falling within control limits. Crosscheck results that fall outside control limits are addressed by formal corrective actions in order to determine any conditions that could adversely affect sample data and to ensure that actual sample results are reliable.

Personnel Training

Anyone performing environmental monitoring program activities is trained in the appropriate procedures and qualified accordingly before carrying out the activity as part of the site environmental monitoring program.

Record Keeping

Control of records is an integral part of the environmental monitoring program. Field data sheets, chain-of-custody forms, requests for analysis, sample-shipping documents, sample logs, bench logs, laboratory data sheets, equipment maintenance logs, calibration logs, training records, crosscheck performance records, data packages, and weather measurements, in addition to other records, are maintained as documentation of the environmental monitoring program. All records pertaining to the program are routinely reviewed and securely stored.

A Laboratory Information Management System (LIMS) is used to log samples, print labels, store and process data, track quality control samples, track samples, produce sampling and analytical worklists, and generate reports. Subcontract laboratories, where possible, provide data in electronic form for direct entry into the LIMS.

Chain-of-Custody Procedures

Chain-of-custody records begin with sample collection. Samples brought in from the field are transferred under signature from the sampler to the sample custodian and are logged at the sample receiving station, after which they are stored in a sample lockup before analysis or shipping.

Samples sent off-site for analysis are accompanied by an additional chain-of-custody/analytical request form. Subcontract laboratories are required by contract to maintain internal chain-of-custody records and to store the samples under secure conditions.

Audits and Appraisals

In 1998 the WVNS Quality Assurance and Environmental Affairs departments provided oversight by conducting audits, assessments, surveillances, and inspections. The areas examined were the environmental monitoring program, the State Pollutant Discharge Elimination System (SPDES) and drinking water monitoring programs, sampling on the north plateau, the activities and quality assurance programs of contract laboratories that analyze samples for the WVDP, the handling, shipping, and releasing of samples, the activities and quality assurance program of the on-site Environmental Laboratory, and the calibration of the meteorological tower.

Self-Assessments

Routine Self-assessments. Routine self-assessments of the environmental monitoring program were conducted in 1998. The primary topics addressed by the assessments were field sample documentation and collection, equipment maintenance and calibration, sample handling and preservation, sample storage and shipping, data management, and data reporting.

No findings were noted; one observation was reported. This deficiency was addressed through formal corrective action procedures. In addition, several comments regarding possible program improvements were noted and commendable practices were identified. Nothing was found during the course of these routine self-assessments that would compromise the data in this report or in the program in general.

Year-2000 Compliance Assessment. A special assessment was conducted in 1998 to determine if environmental monitoring program computer hardware and software were capable of handling data correctly when the year 2000 arrives. Several systems were examined, including the meteorological system, water samplers, air samplers, radiological instruments, emergency response equipment, laboratory and field instruments, laboratory and field support equipment, and data management and reporting systems.

Corrective actions were identified, and a schedule for completing the corrective actions, which includes purchasing new equipment and software, was developed so that all systems will be year-2000 compliant in 1999.

Lessons Learned Program

Information from audits, appraisals, and self-assessments that may be important to WVDP organizations other than the originating department may be shared through the WVDP Lessons Learned Program. The WVDP maintains this system in order to identify, document, disseminate, and use this information to improve the safety, efficiency, and effectiveness of all WVNS operations.

Data Management and Data Validation

Information on environmental monitoring program samples is maintained and tracked in the LIMS and includes date and time of collection, chain-of-custody transfer, shipping information, analytical results, and final validation status.

All software used to generate data is subjected to verification and validation before use. All analytical data produced in the Environmental Laboratory at the bench level are reviewed and signed off by a qualified person other than the one who performed the analysis. A similar in-house review is contractually required from subcontractor laboratories.

Analytical data from both on- and off-site laboratories are formally validated by the data validation group. As part of the validation procedure, quality control samples analyzed in conjunction with a batch of samples are checked for acceptability. After validation is complete and transcription between hard copy and the LIMS is verified, the sample result is formally approved and released for use in reports.

Data Assessment and Reporting

Radiological and nonradiological data from the environmental monitoring program are evaluated in order to assess the effect, if any, of the site on the environment and the public. Data from each sampling location are compared to applicable standards or background measurements.

• Radiological concentrations in liquid effluent releases or air emissions are compared to DOE derived concentration guides (DCGs) for release of water or air to an unrestricted environment. DCGs for specific radionuclides are listed in Table K-1 (p.K-3).

• Calculated doses from air emissions are compared to National Emissions Standards for Hazardous Air Pollutants (NESHAP) limits.

• Nonradiological releases from liquid effluents covered by the SPDES permit are compared to the limits specified in the permit (listed in Table G-1 [pp.G-3 and G-4]).

• Near-site radiological results are compared to results from background locations far from the site.

• Results from surface waters downgradient of the site are compared to results from upgradient locations.

Standard statistical methods are used to compare the data. Where possible, the underlying distribution of the data set is assessed before determining the appropriate statistical tests to be used.

Once the data have been evaluated reports are prepared. Calculations summarizing the data, e.g., summing the total curies released from an effluent point, averaging the annual concentration of a radionuclide at a monitoring point, or pooling confidence intervals from a series of measurements, are made in accordance with formally approved procedures. Final data are reported as described elsewhere in this report. (See Data Reporting [p.1-4] and the section on Scientific Notation at the back of this report.)

Before each technical report is issued the document, including the data, is comprehensively reviewed by one or more persons who are knowledgeable in the necessary technical aspects of the field of work.

Summary

The multiple levels of scrutiny built into generating, validating, evaluating, and reporting data from the environmental monitoring program ensure that reliable data are reported. The quality assurance elements described in this chapter ensure that environmental monitoring data are consistent, precise, and accurate. The effectiveness of the monitoring program is evidenced by continuing favorable quality assurance assessments.